K003274 APR - 6 2001

510(k) Summary of Safety and Effectiveness
[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Submitted January 18, 2001

Contact: PLUS ORTHOPEDICS
3550 General Atomics Ct., Bldg. 15-100
San Diego, CA 92121
Tel: 858-455-2400
Attn: Mr. Hartmut Loch, RAC
Director of Regulatory Affairs

Trade name: LPC-PLUS Acetabular Cup

Common name: Cementless Acetabular cup

Classification name: Prosthesis, hip, semi-constrained, metal/polymer, uncemented. Class II

Product Code: LWJ & LZO, Orthopedic Device Panel 87

Equivalence: The LPC-PLUS Acetabular Cup is substantially equivalent to the DePuy Duraloc® 300 SERIES Acetabular Cup, which was cleared for marketing by the FDA on April 18, 1995 (K951301). Both cups are "low profile" tri-spiked cups made of titanium with a Titanium Plasma coating. Both cups are used for the same indications and are available in similar shapes and sizes. The only difference between them is the type of titanium and the sterilization method (LPC-PLUS is CPTi and gamma sterilized; the Duraloc® is Ti-6AL4V Alloy and gas plasma sterilized).

Device Description and Characteristics: The LPC-PLUS Acetabular Cup is a surface treated titanium acetabular cup made from commercially pure titanium. To improve primary stabilization the surface is treaded with a CP titanium vacuum plasma spray coating. In addition, there are three spikes placed along the periphery and a central peg in the dome of the cup. The centralizing hole of the central peg can be closed from the inside with a M6 locking screw (3.5 mm).

Where indicated, PLUS cancellous bone screws may be used for additional cup fixation. All materials conform to ASTM F 67-95 and ISO 5832-2. The LPC-PLUS cup is available in 17 sizes, 40 mm through 72 mm, in 2 mm increments. The inserts to be used with the LPC-PLUS acetabular cup are made of UHMWPE according to ASTM F-648 and ISO 5834-1/2. The bone screws made of Ti6Al4V according to ASTM F67-95 are already commercially available in the U.S.A. for the following acetabular cups:

EPF®-PLUS Ti-Plasma Coated Cup	K994146 - S/E 12/11/00
EPF®-PLUS Acetabular Cup	K972931 - S/E 11/13/97
PLUS-FIT™ Acetabular Cup	K973077 - S/E 11/13/97
BOFOR® Revision Cup	K993874 - S/E 6/5/00

Indications:	The LPC-PLUS Acetabular Cup is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Numerous biomechanical tests including shear, fatigue strength and abrasion tests have been performed. All test results were equivalent to other similar implants of various manufacturers, and are sufficient for in vivo loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2001

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
3550 General Atomics Court
Building 15-100
San Diego, California 92121-1122

Re: K003274
Trade Name: LPC-PLUS Acetabular Cup
Regulatory Class: II
Product Code: LZO and LWJ
Regulation: 21 CFR 888.3353
Dated: January 18, 2001
Received: January 19, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003274

Device Name(s):

LPC-PLUS Acetabular Cup

Indications for Use:

The LPC-PLUS Acetabular Cup is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003274

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)